UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	**MDL No. 2606**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 15-2606 (RBK)(JS)**

PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF MARIANNE C. MANN

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PRELIMINARY STATEMENT

The testimony of the Defendant's regulatory expert, Dr. Marianne C. Mann, should be precluded from the trial of this matter, because none of her opinions pertain to the relevant issue at hand, i.e., whether there is a causal association between Olmesartan and gastrointestinal symptoms. This Court has indicated that causation will be the lone issue at the upcoming trial in this matter and the Court has expressly directed the parties to focus on causation during the course of expert discovery. Dr. Mann offers seventeen (17) separate opinions in the conclusion section of her written report, but none of these opinions pertain to the issue of causality. *See*, Expert Report of Marianne Mann, attached as "Exhibit A" at pp. 29-32. Instead, Mann's opinions relate only to the appropriateness of Defendant's conduct in warning consumers of the risks of Olmesartan. *Id*. at pp. 29-32. At the outset of her written report, Mann acknowledges the Court's directive to focus on issues of causation[1] but, despite her apparent understanding of the Court's instructions, Mann's report is devoid of any opinions relating to causality. *Id*. Significantly, at her expert deposition in this case, Mann repeatedly confirmed that she was not and could not offer any opinions relating to causation and steadfastly insisted that she would not answer any questions relating to causation. *See*, Excerpts of Deposition Testimony of Marianne Mann, attached as "Exhibit B."

Pursuant to Federal Rule of Evidence 702, an expert witness will not be permitted to testify unless the expert's scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue. Moreover, as this Court has often explained, to be admissible, expert testimony must "fit" the particular case. In other words,

[1] In the opening paragraph of her report Mann states, "***My understanding is that the Court has asked the parties to only address issues of causation at this time*** and my report will focus on those issues from an FDA regulatory perspective." See, "Exhibit A" at p. 1.

there must be a connection between the expert's scientific research and the issues in the case. Here, the issue for the trier of fact is whether Olmesartan causes gastrointestinal symptoms. There is no connection whatsoever between Mann's opinions regarding corporate conduct and the causation issue. Therefore, her opinions do not fit this case and will not assist the trier of fact.

I. THE *DAUBERT* STANDARD

Federal Rule of Evidence 702, which incorporates the *Daubert* standard governs the admissibility of expert testimony in Federal Court. The Rule states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the fact of the case.

Fed.R.Evid. 702. "Rule 702 has a liberal policy of admissibility." *Geiss v. Target Corp.*, 2013 *WL* 4675377 at *4 (D.N.J. 2013), citing *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008), other citations omitted. This Court has set forth the three criteria to be satisfied:

> To be admissible, expert testimony must satisfy three requirements under Rule 702: 1) the witness must be an expert (i.e., must be qualified); 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge (i.e., must be reliable); ***and 3) the expert's testimony must assist the trier of fact (i.e., must fit)….*** An expert is qualified if he possesses specialized expertise. The qualification requirement is liberally construed. *Id*. (Emphasis added).
>
> A reliable opinion is based on the 'methods and procedures of science rather than on 'subjective belief or unsupported speculation; the expert must have 'good grounds' for his or her belief…. The focus of the reliability inquiry is on the expert's principles and methodology, not on his conclusions…. In determining reliability, a court may look to several non-exhaustive factors, including:
>
> > (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non judicial uses to which the method has been put.

> Finally, an opinion fits a particular case (and thus helps the trier of fact) when there is a connection between the scientific research or test result to be presented and particular disputed factual issues in the case…. Fit is an issue of relevance and simply means that scientific validity of the method or principles applies to the issues at hand….

Geiss v. Target Corp., at *4-5, citations omitted. The listed factors are not exhaustive or determinative and must be applied flexibly, placing the "principles and methodology" applied above the actual conclusion reached. *Daubert v. Merrell Dow Pharmaceuticals*, 509 *U.S.*, 769 595 (1993); *Kumho Tire Co. v. Carmichael*, 525 *U.S.* 137, 141, 150 (1999).

In elucidating the second requirement of Rule 702, *Daubert* stressed the importance of the "fit" between the testimony and an issue in the case: "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." 509 U.S. at 591 113, S.Ct. at 2796. This is typically understood in terms of whether there is a sufficient 'fit' between the expert's testimony and the facts that the jury is being asked to consider." *United States v. Schiff*, 602 F.3d 152, 172-73 (3d Cir. 2010)(citing *Daubert*, 509 U.S. at 591). *See also In re: TMI Litigation*, 193 F.3d 613, 670 (3d Cir. 1999). This factor is about relevance. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18).

II. LEGAL ARGUMENT

A. Dr. Mann's Opinions Should be Precluded Under Rule 702 of the Federal Rules of Evidence Because Her Opinions Do Not Assist the Trier of Fact in Determining a Fact at Issue.

On January 31, 2017, Defendant's regulatory expert, Marianne C. Mann, M.D. ("Mann") authored a written report in this case which contains seventeen (17) separate conclusions. *See*, "Exhibit A" at pp. 29-32. In essence, Mann concludes that Defendant acted appropriately in

assessing the association between Olmesartan and gastrointestinal disorders and implemented labeling revisions in a timely manner. *Id.* at 29-32.

At her deposition, Mann was specifically and repeatedly asked her opinion about whether there is an association between Olmesartan and gastrointestinal problems and whether there is indeed a causal relationship. However, as noted above, Mann consistently testified that she was not offering, and indeed could not, offer causation opinions in this case. She made clear that she was only opining on regulatory issues. Specifically, Mann testified in relevant part as follows:

> Q. So if I were to define causality assessment by saying it's the determination of whether there is reasonable possibility the drug is etiologically related to the Adverse Event, causality assessment includes, for example, assessment of temporal relationships, dechallenge/rechallenge information, association with or lack of association with underlying disease presence or absence of a more likely cause plausibility, et cetera, is that a -- is that a complete or incomplete definition?
>
> MR. URQUHART: Objection to the form of the question.
>
> A. Yeah. I think you're asking me about a definition of medical causality, and I'm here to talk about regulatory assessments of when a label is changed and when a drug is felt to be possibly linked or associated with a drug Adverse Event, and ***I don't feel I'm able to answer some of the questions you're posing to me because I think they are about medical causality, and I'm not here as a medical causality expert.***

"Exhibit B" at 95:19 – 96:16 (Emphasis added).

> Q: Correct, but I'm asking you – I'm asking you a question, which can be answered "yes," "no," or "I don't know," and that is, do you believe that there is a reasonable -- that there is reasonable evidence of a causal association between olmesartan and chronic diarrhea?
>
> MR. URQUHART: Objection to the form of the question; further objection, asked and answered.
>
> A. Again, I'm not here to answer causality questions as a medical causality expert. I'm here to answer labeling, and I think I've answered that multiple times.

"Exhibit B" at 201:1-13

> Q. So -- strike that. My question was, you don't render an opinion with respect to causation in this case, correct?
>
> …
>
> A. Yeah. I am here to provide perspective on the FDA regulatory process and how they review adverse events and assess if their causally associated with a drug and whether labeling changes need to be made. And I'm here, in part, I think, based on Dr. Kessler's report to sort of address what he addresses from a regulatory perspective, but I'm not here for specific medical causation questions.
>
> Q. Okay. So do you have an opinion one way or the other as to whether or not Olmesartan causes symptoms like chronic diarrhea, substantial and significant weight loss, nausea, vomiting?
>
> MR. URQUHART: Objection to the form of the question.
>
> A. ***I'm not here to answer medical causality questions, so no, I don't have an opinion about that***.

"Exhibit B" at 180:20 – 182:4 (Emphasis added).

Mann's testimony makes clear that her opinion simply does not "fit" the issue that will be before the jury at this stage, and therefore will not assist the jury in reaching its conclusion in this case. In fact, Mann's testimony will only serve to confuse and mislead the jury. As set forth above, admissibility depends in part on the "connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *United States v. Downing*, 753 F.2d 1224 (3d Cir., 1985). *See Daubert*, 509 U.S. 579, 113 S.Ct. at 2795–96 (explicitly adopting the "fit" requirement of *Downing*). The *Daubert* court instructed that, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case. Id.* at 591 113 S.Ct. at 2796."

As this Court has noted, "fit" is an issue of relevance, i.e., that it logically advances a material aspect of the proposing party's case. *Geiss v. Target Corp.*, at *4-5, citations omitted

"Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18).

Conversely, Plaintiff's FDA regulatory expert, Dr. David Kessler ("Kessler") does offer opinions relating to causal association in this case. For example, in his expert report, Dr. Kessler opines that at least by 2007, there was reproducible positive de/rechallenge evidence that met the FDA standard of reasonable evidence of a causal association. *See*, Expert Report of David Kessler, attached as "Exhibit C." Similarly, at his deposition, Dr. Kessler testified that by 2007 there was reasonable evidence of a causal association between Olmesartan and serious gastrointestinal symptoms. *See*, "Exhibit D" at 277:13-284:5. Furthermore, at his deposition, Kessler testified with respect to causality as follows:

> It -- to me, just so you understand, my opinion doesn't really hang, again, whether this is 60 or 59 or you want to argue one or two cases, when you -- when I read these as a whole, there is no doubt that olmesartan causes -- I mean, I would -- get a -- get a GI to read these cases. When you read this as a whole, what strikes you, right, is clearly **there is causality here in these cases when you read it as a whole**. A difference of one case or another case would not have made a difference to me.
>
> I'm looking to see what, in fact, was in front of DSI at the time, so if I was sitting there in pharmacovigilance and I took this binder and I read this binder, right, **could I come to any other conclusion than causality, right. And I think that when you read these cases, if you are a clinician, you can't**.

"Exhibit D" at 217:15-26; 219:20 – 220-1 (Emphasis added).

In the instant case, Mann's opinions will not help the trier of fact to understand the evidence or to determine a fact in issue. Her opinions do not fit the inquiry, and thus should be precluded.

CONCLUSION

For the foregoing reasons, Dr. Mann should be precluded from offering the opinion that Olmesartan does not cause Olmesartan-induced enteropathy in some people.

Respectfully,

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CERTIFICATE OF SERVICE

I, Steven D. Resnick, Esquire, hereby certify that on this **31st** day of **March 2017,** a true and correct copy of Plaintiffs' Motion to Exclude the Testimony of Marianne C. Mann was filed via the Court's CM/ECF Filing system which generates an electronic notice to all counsel of record.

I hereby further certify that I caused and true courtesy copies of Plaintiffs' Motion to Exclude the Testimony of Marianne C. Mann to be served on the parties below via Federal Express Standard Overnight Delivery:

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